APPENDIX A

Legislative Overview

Legislative Overview

Background/History

Birth defects are the leading cause of infant mortality and were the sixth leading cause of potential years of life lost before age 65 (Watkins et al, 1996). Birth defect surveillance makes it easier to track changes in incidence and unusual patterns that could be caused by environmental factors. Birth defect surveillance activities assisted in the development of health policies, planning and prevention activities in surrounding states in the U.S. (Watkins et al, 1996).

Birth Defects legislation first began in the 1920s in the state of New Jersey, and interest concerning birth defects surveillance began in the 1960s. However in 1978, only three state surveillance programs existed in the United States. Recently the strong efforts of such agencies as the March of Dimes have caused a dramatic increase in birth defects surveillance legislation in Congress. In 1992, the first bill was passed authorizing national birth defects legislation (Edmonds et al, 1997). More specifically, the bill authorized:

- ?? A national birth defects surveillance and prevention research system
- ?? Efforts to broaden public and professional awareness of birth defects and their prevention
- ?? State-wide birth defects prevention and intervention programs.

The bill was amended in 1992 including the development of collection and analysis of epidemiological data on birth defects and a national clearinghouse to collect and distribute information on birth defects (Edmonds et al, 1997).

The 1998 Birth Defects Prevention Act expanded the activities of previous legislation to include a program to collect, analyze and report statistics on birth defects, the implementation of five regional centers to conduct applied epidemiological research on prevention of birth defects, and multi-year budget allocations. Currently, over half of the 50 states making up the United States have or are implementing birth defects surveillance programs (Erickson, 1997).

Newborn screening is the first and largest genetic program for children and began through state programs in the 1960s. Newborn screening is comprised of five components (testing, follow-up, diagnosis, treatment, and evaluation) and the extent of screening is state-based (AAP Newborn Screening Task Force, 2000). Newborn screening programs in the U.S. test an estimated four million infants annually for genetic disorders. Although all states and territories of the United States have a newborn screening program, considerable variability exists in the systems available for follow-up, the genetic disorders included in the screening system, the laboratory capability within the state, treatment protocols, and mandated follow-up services. The lack of standardization highlights the need for a national newborn screening program (Hiller et al, 1997).

All 50 states today screen infants for at least two disorders, pheynlketonuria (PKU) and congenital hypothyroidism. There is significant inconsistency in screening beyond these two tests, and without nationally mandated standards, infants across the U.S. will have inequitable access to newborn screening (AAP Newborn Screening Task Force, 2000).

Lobbying efforts by both health professionals and parents continue to dramatically increase planned legislation and programs concerning genetics conditions testing and services in the U.S.

Summary of Legislative Activities

Laws and regulations concerning genetic conditions testing are determined at the state level, and states have considerable latitude to design programs to fulfill legislative parameters. Following are specific summaries of current legislation concerning genetics disorders testing for newborns and children in each state within Region 5 (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin) of the U.S and three other states (Hawaii, Iowa and Oregon) that have genetics screening programs that are more mature than Indiana's and are based on "active" surveillance.

Illinois – In 1965 Illinois began screening of all newborns for PKU. In 1979 the screening program was expanded to include hypothyroidism. The Illinois State Department of Health (IDPH) received federal funding in 1983 for the creation of a statewide Clinical Genetics Network in an effort to make genetic services accessible to all citizens in the state. The newborn screening program was expanded again in 1984 to include galactosemia, biotinidase, and congenital adrenal hyperplasia. In 1988 the six Clinical Genetic Centers were added with funding from a Maternal and Child Health Services block grant. The newborn screening program was awarded a federal grant in 1989 to implement universal newborn sickle cell disease to its screening. Funds were provided to 13 public health departments in 1990 to establish a network of local agencies to coordinate follow-up services for families of infants with an abnormal newborn screening test. In 1994 the network of Clinical Genetic Centers was expanded to 38 regional centers, and in 1995 Illinois was one of three states to receive a grant from the Centers for Disease Control (CDC) to evaluate the impact of their newborn screening program. A pilot study was conducted in 1999 to test the capability of new technology to screen for up to 30 different inherited metabolic conditions with a single test. As of 2000, the network of Clinical Genetic Centers included 69 agencies that collaborate to ensure all families have access to genetic services. Illinois currently includes seven conditions in its newborn screening program. Today, with more tests added to the roster, it is estimated that more than 200 infants each year will be identified as having one of these conditions and will be referred for early treatment and follow-up services. Although the newborn screening test is required by state law, an exception can be made due to religious beliefs if the parent signs a statement (Illinois Department of Public Health, 2001).

Indiana – Indiana currently includes eight conditions in its newborn screening program. Current legislation directs health professionals in charge of the care of newborn infants to administer a test for each of the following: phenylketonuria, galactosemia, homocystinuria, hypothyroidism, maple syrup urine disease, biotinidase deficiency, hemoglobinopathies-including sickle cell anemia, and congenital adrenal hyperplasia. Current laws also provide that a physician may order that a newborn be confidentially tested for the human immunodeficiency virus (HIV) or for antibodies to HIV if the mother has not been tested, the mother refuses to have the newborn infant tested, and the physician believes that the test is

medically necessary for the newborn infant. The act does allow the test to be refused for religious reasons. The law also requires that the mother be notified of the test, receive counseling and information, and receive the confidential test results. It also requires the state Department of Health to apply for federal funds to pay for newborn HIV testing. The Indiana State act appropriates money for newborn HIV testing. The Newborn Screening Program strives to assure that all infants born in Indiana are tested for designated genetic disorders. Initially, Indiana Code 16-41-17 requires that the Indiana State Department of Health (ISDH) maintain a centralized program that provides diagnosis, follow-up, management, family counseling and support, including equipment, supplies, formula and other materials, for all infants and individuals identified as having the following conditions: phenylketonuria (PKU) galactosemia, maple syrup urine disease (MSUD), homocystinuria, hypothyroidism, hemoglobinopathies including sickle cell (National Conference of State Legislatures, 2000). Two additional conditions were added in 2000: congenital adrenal hyperplasia and biotinidase deficiency.

In 2001, the Indiana General Assembly amended the Indiana Code regarding newborn screening (HEA 1487). This code change enables ISDH to include in the mandatory newborn screens any disorders detected by the tandem mass spectrometry. Implementation guidelines are currently being developed.

Also this legislative session, HEA 1864 was passed which allows ISDH to expand its Birth Problems Registry to require reporting until the child is 2 years of age. However, ISDH is not required to implement this until funding is available to do so.

The program in Indiana has grown through the years. Indiana first began testing in 1965 for phenylketonuria only. In 1978, testing was added for hypothyroidism. Then in 1985, subsequent tests were mandated for galactosemia, maple syrup urine disease, and homocystinuria. In 1987, the Newborn Screening Fund was established to finance the Newborn Screening Program, including a quality assurance program for the Newborn Screening Laboratory. In 1990, the Indiana General Assembly authorized the program to purchase dietary formula for infants diagnosed as having phenylketonuria. All infants born in Indiana are required to have blood obtained for newborn screening. The only acceptable reason for refusing the screen is an informed refusal on religious grounds. Infants normally have a screening specimen collected at least 48 hours after birth. All newborn screen blood specimens, together with required medical and demographic information, are forwarded to the ISDH designated laboratory for processing. The laboratory currently so designated is the Indiana University Medical Center Newborn Screening Laboratory (IU-NBS Lab).

The results of all screens are reported by the IU-NBS Lab to the infant's attending physician, the birthing institution (hospital), and the Newborn Screening Section within the Indiana State Department of Health. In the case of unacceptable screens or screens having abnormal results, a repeat screen is required. If the responsible hospital or physician is unable to obtain the repeat screen, additional follow-up is initiated by the ISDH, which may include requesting assistance from local health officials. Cases are considered open until a valid screen is done with normal results, or the infant is confirmed to have one of the eight genetic conditions and

is verified to be undergoing appropriate treatment/family counseling (Indiana State Department of Health).

Michigan – As of year 2000 Michigan includes seven genetic conditions in its newborn screening program. Statutes direct health professionals in charge of the care of newborn infants to administer a test for each of the following: phenylketonuria, galactosemia, hypothyroidism, maple syrup urine disease, biotinidase deficiency, sickle cell anemia, congenial adrenal hyperplasia, and other treatable but otherwise disabling conditions as designated by the department. The department may charge a fee of not more than thirty-nine dollars ($39.00) for the test, with a provision for a hardship waiver.

A second law provides that a health professional may offer to draw an additional blood specimen from the infant. If the infant's guardian accepts the offer, the blood specimen must be preserved in a manner that does not require special storage conditions or techniques. The health professional must explain to the guardian that the additional blood specimen can be stored for future identification purposes and should be kept in a safe place. The health professional may charge a fee that is not more than the actual cost of obtaining and preserving the additional blood specimen.

A third law mandates a physician to take test specimens of a pregnant woman, at the time of her initial examination, and submit the specimens to a clinical laboratory for the purpose of performing tests approved by the department for venereal disease, HIV or an antibody to HIV, and for hepatitis B. If, when a woman presents at a health care facility to deliver an infant or for care in the immediate postpartum period having recently delivered an infant outside a health care facility, no record of results from the tests required by this subsection is readily available to the physician, then the physician shall take specimens of the woman and shall submit the specimens to a clinical laboratory for tests. The test results and the records are not public records, but shall be available to a local health department and to a physician who provides medical treatment to the woman or her offspring (National Conference of State Legislatures, 2000).

Minnesota – Minnesota currently includes five genetic conditions in its newborn screening program, and requires the commissioner of health to develop a statewide birth defects registry system to provide for the collection, analysis and dissemination of birth defects information. The purpose of the registry is to monitor the trends in birth defects, investigate clusters of birth defects to address concerns with scientific data, identify cases of birth defects for study to establish a cause, increase public awareness and evaluate the effectiveness of certain prevention programs (National Conference of State Legislatures, 2000).

Ohio – Ohio currently includes five genetic conditions in its newborn screening program and requires the Public Health Council to include in its rules prescribing laboratory tests to detect phenylketonuria in newborns and any test that it determines is effective to detect the disorder in newborns younger than 48 hours old (National Conference of State Legislatures, 2000).

Wisconsin – Wisconsin's Newborn Screening Program, which started in 1965, strives to provide the best service possible for infants and their families. Newborn screening began with testing for phenylketonuria (PKU).

Currently, the program screens for 21 disorders. In addition to testing all newborns for these disorders, the program plays a crucial part in the care of infants who are diagnosed with these conditions.

The Newborn Screening Program, administered by the Wisconsin Department of Health and Family Services, has a Newborn Screening Advisory Group whose members include health care professionals, public health professionals, and parents. This group's role is to help ensure that the program succeeds in screening, diagnosing, and treating all Wisconsin newborns for a variety of treatable conditions present at birth.

Wisconsin law requires that all babies born in hospitals in Wisconsin have newborn screening before they leave the hospital. Babies born at home must be tested within a week of birth (Wisconsin Department of Health and Family Services, 2001).

Parents may refuse newborn screening only if their religious beliefs and practices do not allow testing (National Conference of State Legislatures, 2000).

Hawaii - Hawaii's newborn screening began in 1965 with the passage of legislation that mandated screening of all newborns for phenylketonuria (PKU). In 1983, screening for congenital hypothyroidism was added. In 1985, the Legislature amended the existing statutes to allow the State Department of Health (DOH) to "specify diseases to be screened for in newborn infants and methods to be employed to best prevent mortality and morbidity within the population of the state." It further mandated the DOH to adopt Administrative Rules necessary to fulfill the purposes of the statute. On 1/24/87, the Hawaii Administrative Rules for newborn screening were adopted. In 1996, legislation was passed (Act 259), which established a newborn screening special fund. This legislation makes it possible for the Newborn Metabolic Screening Program (NBMSP) to collect fees, contract with a centralized laboratory, and expand the newborn screening testing panel to seven tests, which includes PKU, congenital hypothyroidism, congenital adrenal hyperplasia (CAH), galactosemia, sickle cell and other hemoglobinopathies, biotinidase deficiency, and maple syrup urine disease (MSUD). The Revised Hawaii Administrative Rules, adopted on June 19, 1997, were amended to reflect these changes. Newborn screening laboratory centralization, expanded newborn screening testing, and newborn screening fees of $27 per newborn screening kit became effective on 7/1/97.

Hawaii's Newborn Metabolic Screening Program is administered through Children with Special Health Needs Branch (CSHNB), Hawaii State Department of Health. The NBS Program has statewide responsibilities for assuring that all infants born in the State of Hawaii are tested for PKU, congenital hypothyroidism and other diseases that are added to the screening panel. The NBS Program tracks and follows up infants to assure satisfactory testing and to assure that infants with the specified diseases are detected and provided with appropriate and timely treatment. The objectives are to prevent and ameliorate the effects of

handicapping conditions that are identified through the administration of newborn screening and diagnostic testing.

All newborn screening specimens for infants born in the State of Hawaii are sent to the **Oregon State Public Health Laboratory (OSPHL)** for newborn screening testing.

Preliminary analysis of the Newborn Screening Registry, established in 1986, shows that the number of PKU and congenital hypothyroid cases in Hawaii is at least the same magnitude as reported nationally (Hawaii Department of Health).

Iowa - The Iowa legislature created the Birth Defects Institute (BDI) within the Iowa Department of Public Health (IDPH) in 1976. The BDI, in partnership with the University of Iowa and health care providers throughout the state, has developed programs that provide Iowans with the most advanced genetics health care.

Presently, there are five programs within the BDI: the Regional Genetic Consultation Service, the Iowa Neonatal Metabolic Screening Program, the Expanded Maternal Serum Alpha-fetoprotein Screening Program, the Iowa Birth Defects Registry, and the Neuromuscular and Related Genetic Diseases Program.

The Birth Defects Advisory Committee (BDAC), which is composed of representatives from the involved programs, various professional health care groups, consumers, two legislators, and a representative of the IDPH, acts in an advisory capacity to the programs of the Birth Defects Institute. Activities of the BDI are coordinated at the Iowa Department of Public Health by the State Coordinator for Genetic Services.

The Iowa Neonatal Metabolic Screening Program (INMSP) screens for six disorders: phenylketonuria, congenital hypothyroidism, galactosemia, congenital adrenal hyperplasia, the hemoglobinopathies, and medium chain acyl-CoA dehydrogenase deficiency (MCAD).

Newborn metabolic screening is required by Iowa law and must be completed before discharge from the hospital. The INMSP is a fee-for-service program with laboratory, comprehensive care and educational components. The University Hygienic Laboratory is the central screening laboratory. A comprehensive follow-up program at the University of Iowa, Department of Pediatrics, provides families and their physicians with the expertise necessary to manage identified disorders (Iowa Department of Public Health, 2001).

Oregon – Oregon currently screens newborns for seven disorders. The Newborn Screening Program screens newborns for metabolic, endocrine, and hemoglobin disorders -- identifying infants who need immediate treatment to prevent developmental problems, mental retardation or death. Identified infants are tracked to ensure they receive appropriate medical care.

The state provides a manual for parents that explains the screening program and is distributed when babies are discharged from the hospital. It contains information about the importance of newborn screening as well as the best time for the second specimen to be drawn (7 - 21 days) (Oregon Health Department, 2001).

The Newborn Screening Program distributes a manual to all doctors, midwives, nurse practitioners and laboratorians who work with newborns. It includes information about screening practices, specimen collection, educational services, as well as more information about each of the following disorders:

biotinidase deficiency
congenital adrenal hyperplasia (CAH)
galactosemia
hemoglobinopathies (like sickle cell disease)
hypothyroidism
maple syrup urine disease (MSUD)
phenylketonuria (PKU) [12]

Table 1 describes genetic conditions included in newborn screening programs for all 50 states.

Table 1. U.S. National Screening Status Report, 2001*
The National Screening Status Report lists the status of newborn screening in the United States.
All infants in a state must be screened in order for a dot to be added.
* Only Indiana's data are from the 2001. All other states data were compiled in July 2000.

State	Phenyl-ketonuria (PKU)	Congenital Hypo-thyroidism	Galactosemia	Maple Syrup Urine Disease	Homocystinuria	Biotinidase	Sickle Cell Disease	Congenital Adrenal Hyperplasia	Other
Alabama	?	?	?				?	?	
Alaska	?	?	?	?		?	a	?	
Arizona	?	?	?	?	?	?	?	?	
Arkansas	?	?	?				?	a	6
California	?	?	?				?		6
Colorado	?	?	?			?	?	a	2,6
Connecticut	?	?	?	?	?	?	?		2a,6
Delaware	?	?	?				?		
D.C.	?	?	?	?	?		?		7
Floridia	?	?	?				?	?	6
Georgia	?	?	?	?	?		?	?	3
Hawaii	?	?	?	?		?	?	?	6
Idaho	?	?	?	?		?			
Illinois	?	?	?			?	?	?	6
Indiana	?	?	?	?	?	?	?	?	6
Iowa	?	?	?				?	?	
Kansas	?	?	?	?			?		6
Kentucky	?	?	?	?			?		6

a = Selected population, pilot program, or planning underway
1 = Toxoplasmosis
2 = Cystic fibrosis
3 = Tyrosinemia
4 = Human Immunodeficiency Virus
5 = Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
6 = Mandatory universal hearing screening
7 = Glucose 6-phospate dehydrogenase deficiency (G6PD)

Table 1. U.S. National Screening Status Report, 2001* Continued

* Only Indiana's data are from the 2001. All other states data were compiled in July 2000. The National Screening Status Report lists the status of newborn screening in the United States. All infants in a state must be screened in order for a dot to be added.

State	Phenyl-ketonuria (PKU)	Congenital Hypo-thyroidism	Galactosemia ?	Maple Syrup Urine Disease	Homocystinuria	Biotinidase	Sickle Cell Disease	Congenital Adrenal Hyperplasia	Other
Louisiana	?	?	?			?	?		6
Maine	?	?	?	?	?	?	a	?	5,6
Maryland	?	?	?	?	?	?	?		3,6
Massachusetts	?	?	?	?	?	?	?	?	1,2a,5,6
Michigan	?	?	?	?		?	?	?	
Minnesota	?	?	?				?	?	
Mississippi	?	?	?				?		6
Missouri	?	?	?				?		6
Montana	?	?	?				a		2a
Nebraska	?	?	?			?	?		6
Nevada	?	?	?	?		?	?		
New Hampshire	?	?	?	?	?		a		1,6
New Jersey	?	?	?				?		
New Mexico	?	?	?			?	?	?	
New York	?	?	?	?	?	?	?		4,6
North Carolina	?	?	?				?	?	5
North Dakota	?	?	?					?	

a = Selected population, pilot program, or planning underway
1 = Toxoplasmosis
2 = Cystic fibrosis
3 = Tyrosinemia
4 = HIV
5 = Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
6 = Mandatory universal hearing screening
7 = Glucose 6-phospate dehydrogenase deficiency (G6PD)

Table 1. U.S. National Screening Status Report, 2001* Continued

* Only Indiana's data are from the 2001. All other state's data were compiled in July 2000. The National Screening Status Report lists the status of newborn screening in the United States. All infants in a stat must be screened in order for a dot to be added.

State	Phenyl-ketonuria (PKU)	Congenital Hypo-thyroidism	Galactosemia	Maple Syrup Urine Disease	Homocystinuria	Biotinidase	Sickle Cell Disease	Congenital Adrenal Hyperplasia	Other
Ohio	?	?	?		?		?		
Oklahoma	?	?	?				?		6
Oregon	?	?	?	?		?	?		6
Pennsylvania	?	?		?			?		
Rhode Island	?	?	?	?	?	?	?	?	6
South Carolina	?	?	?				?	?	
South Dakota	?	?	?						
Tennessee	?	?	?				?	a	
Texas	?	?	?				?	?	6
Utah	?	?	?						6
Vermont	?	?	?	?	?	?	?		
Virginia	?	?	?	?	?	?	?		6
Washington	?	?					?	?	
West Virginia	?	?	?				a		6
Wisconsin	?	?	?	a		?	?	?	2,5
Wyoming	?	?	?			?	?		2,6

a = Selected population, pilot program, or planning underway
1 = Toxoplasmosis
2 = Cystic fibrosis
3 = Tyrosinemia
4 = HIV
5 = Medium-chain acyl-CoA dehydrogenase deficiency (MCAD)
6 = Mandatory universal hearing screening
7 = Glucose 6-phospate dehydrogenase deficiency (G6PD)

References

AAP Newborn Screening TaskForce, Elk Grove Village, Illinois. Newborn Screening: A Blueprint for the Future: A Call for a National Agenda on State Newborn Screening Programs. *Pediatrics*. 2000, 106(2).

Edmonds, L.D. 1997. Birth defects surveillance at the state and local level. *Teratology* vol.56: 5-7

Erickson JD. Birth defects surveillance in the United States. *Teratology*. 1997, 56:1-4.

Hiller E. et al. Public participation in medical policy-making and the status of consumer autonomy: The example of newborn-screening programs in the United States. *American Journal of Public Health.* 1997, 87(8).

National Conference of State Legislatures, Maternal and Child Health, Newborn Genetic, Metabolic, and other Disease Screening, April 2000.

Watkins M. et al. The Surveillance of Birth Defects: The usefulness of the revised US standard birth certificate. *American Journal of Public Health.* 1996, 86 (5):731-4.

http://www.dhfs.state.wi.us/

http://www.idph.state.ia.us/

http://www.idph.state.il.us/about/genetics.htm

http://www.ohd.hr.state.or.us/phl/

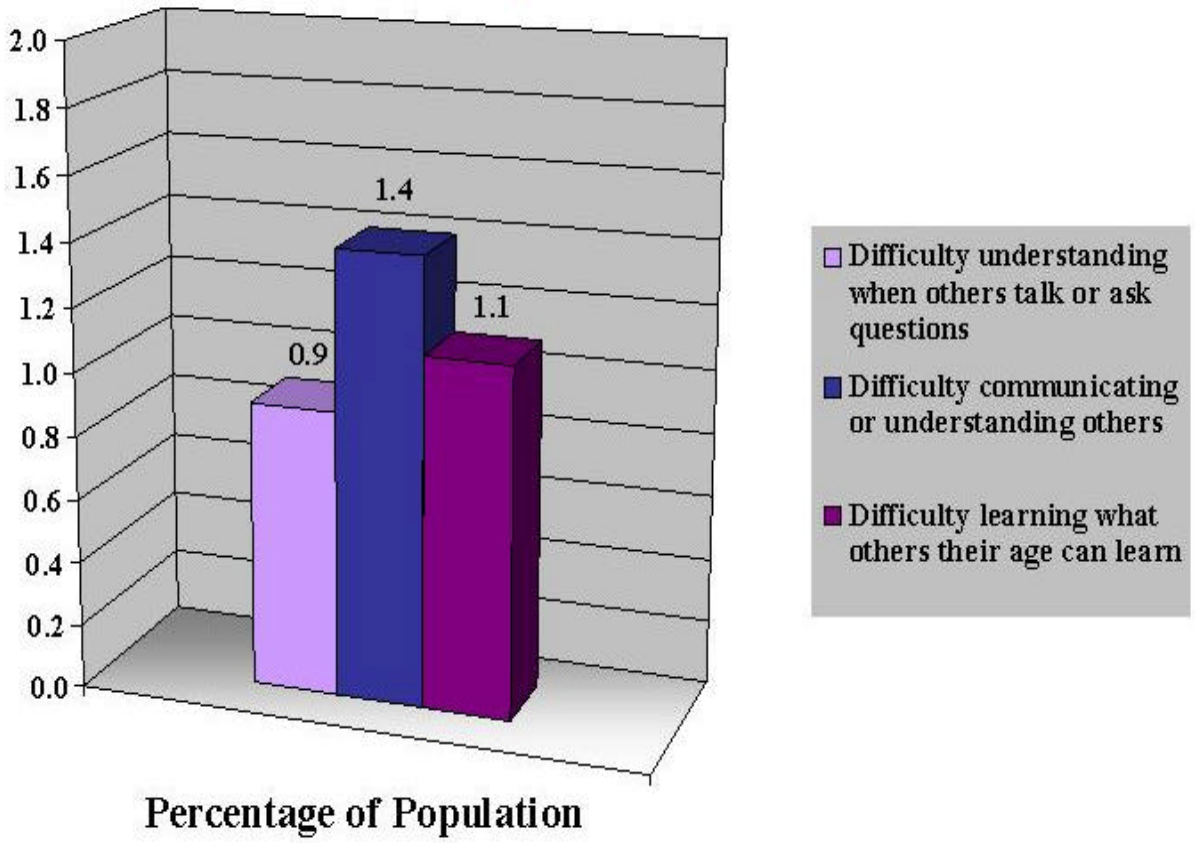
http://www.state.hi.us/doh/

http://www.state.in.us/doh/index.html

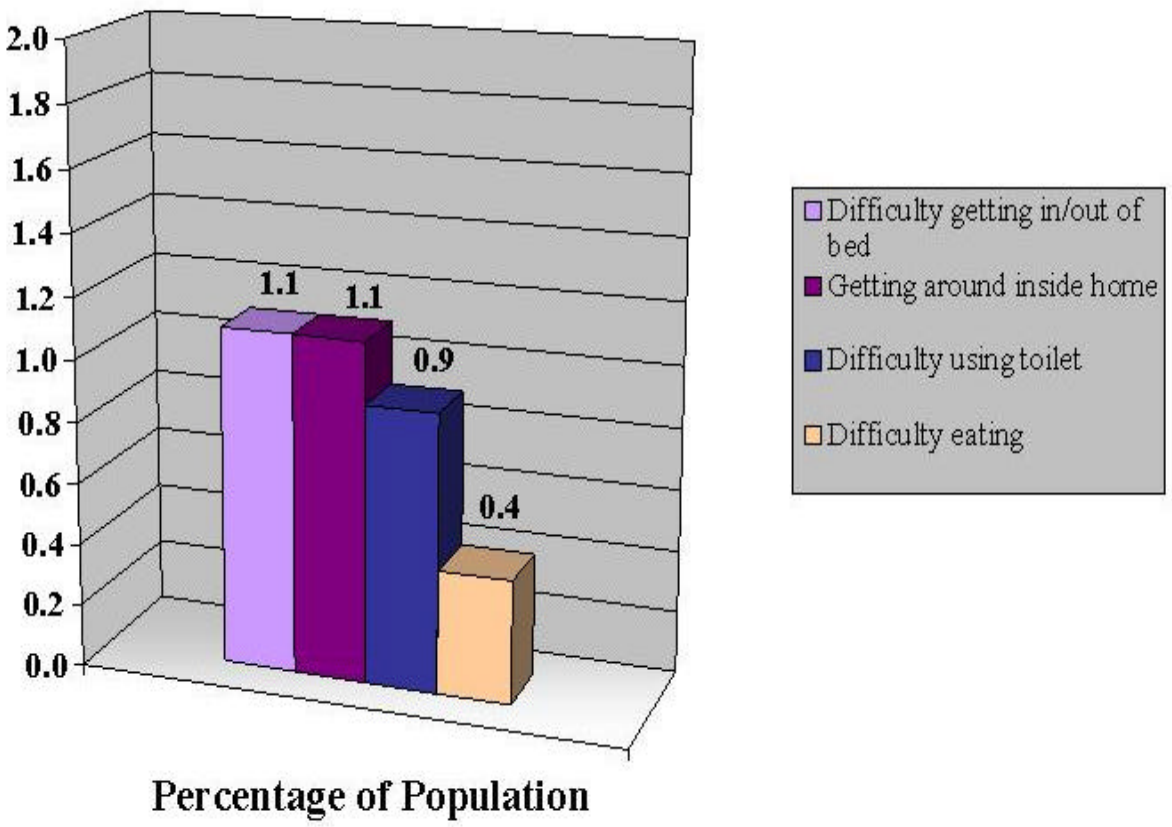
APPENDIX B

Problem Prevalence from the National Study of Health and Disability 1995

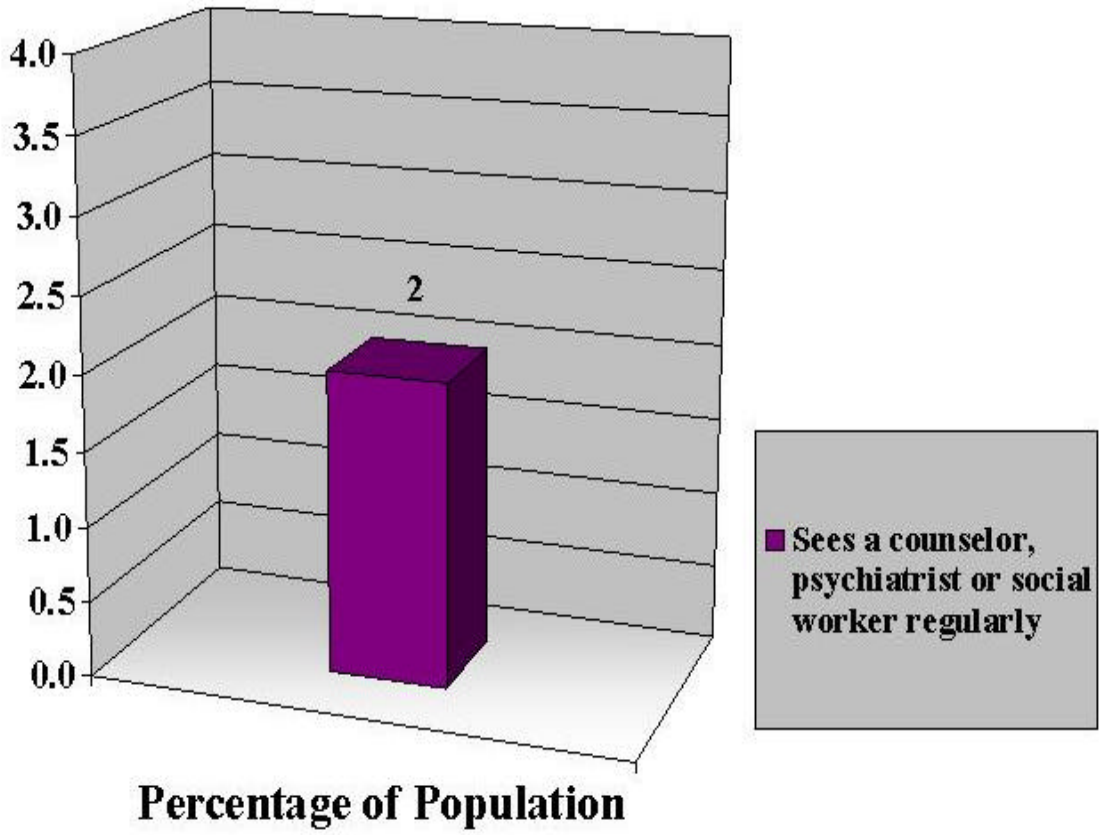
National Study of Health and Disability
Prevalence in Population 5 Years & Older



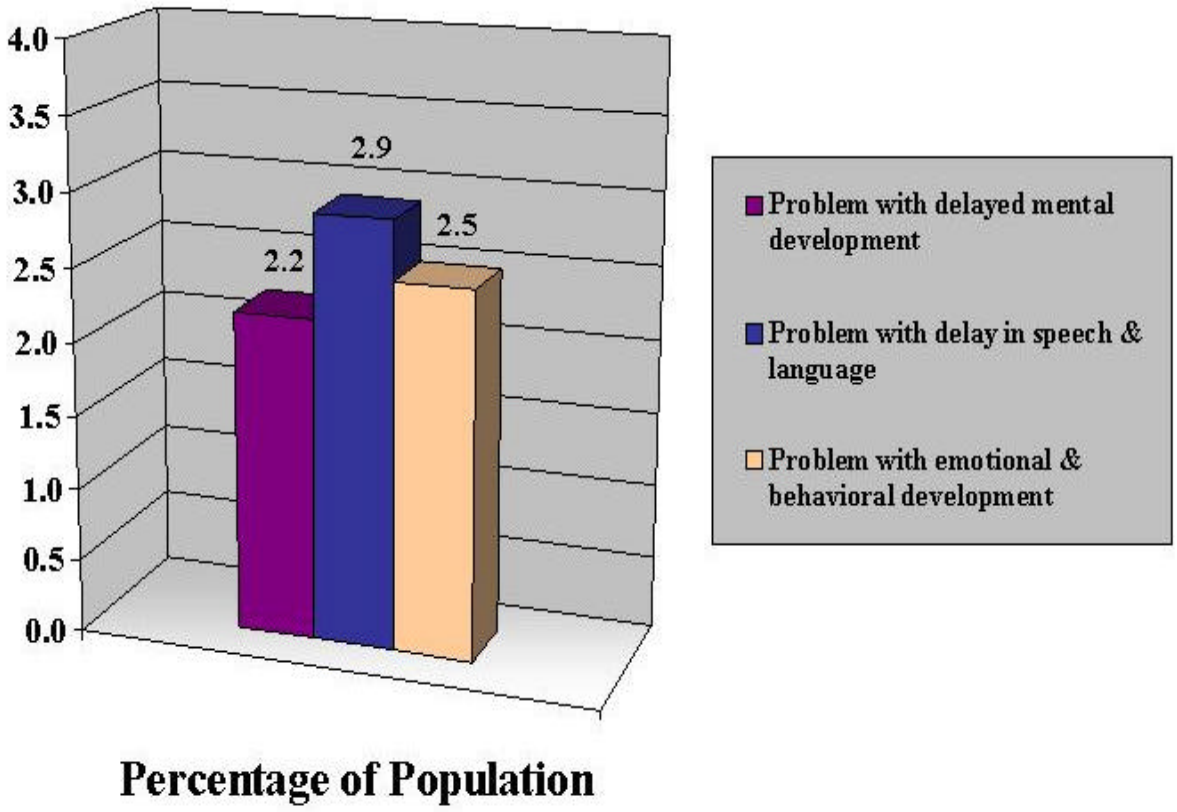
National Study of Health and Disability
Prevalence in Population 5 Years & Older



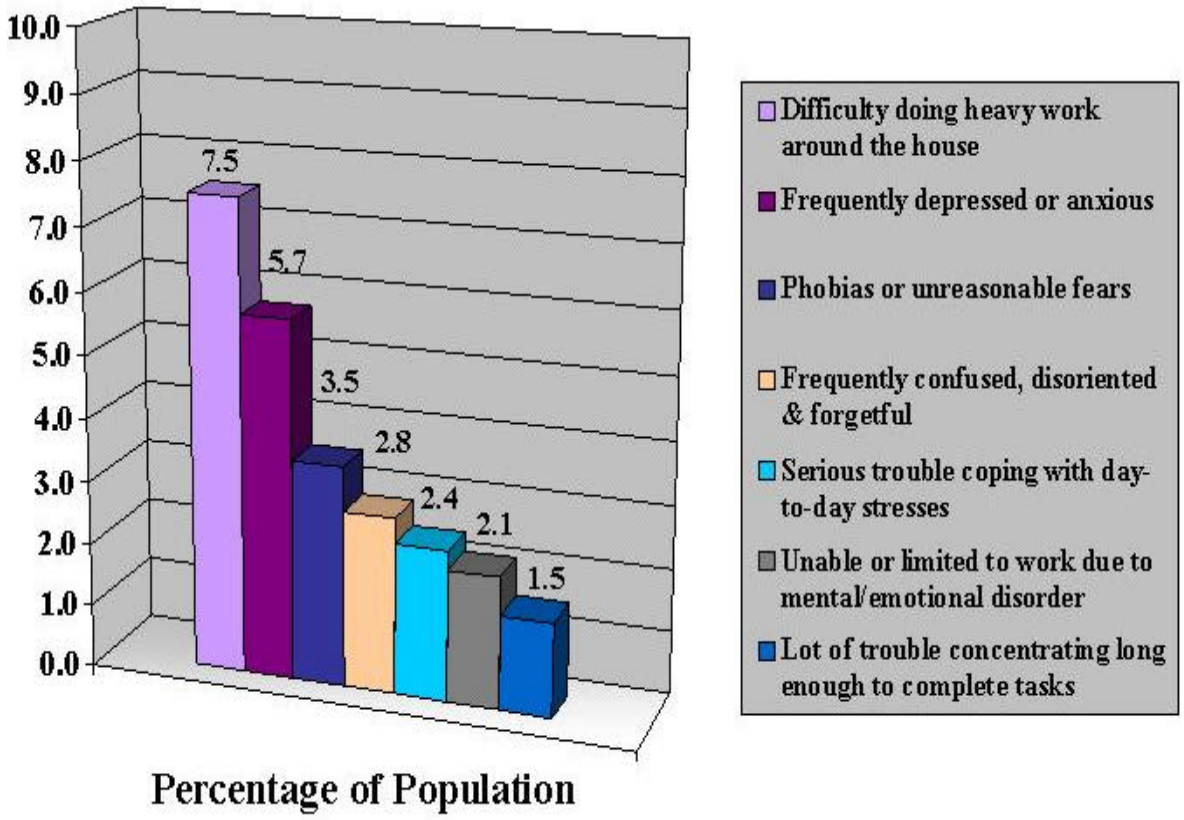
National Study of Health and Disability
Prevalence in Population 17 Years or Younger



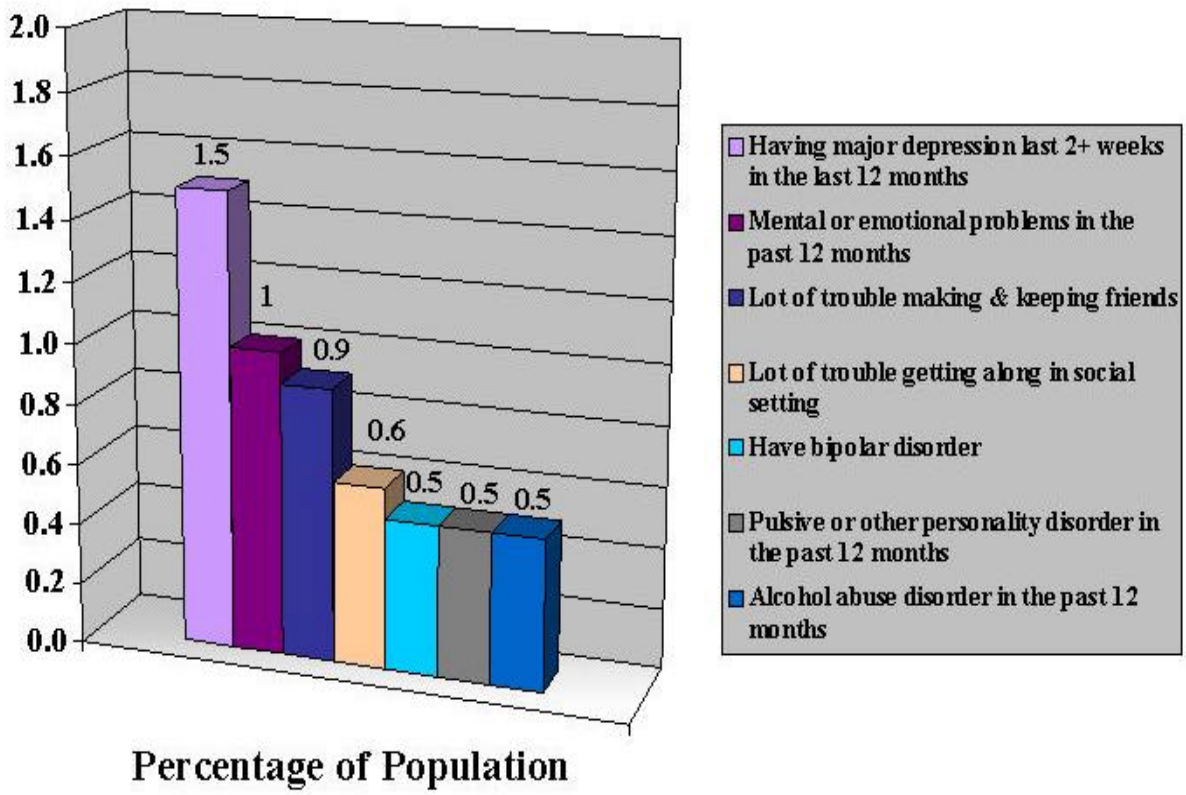
National Study of Health and Disability
Prevalence in Population 2-17 years



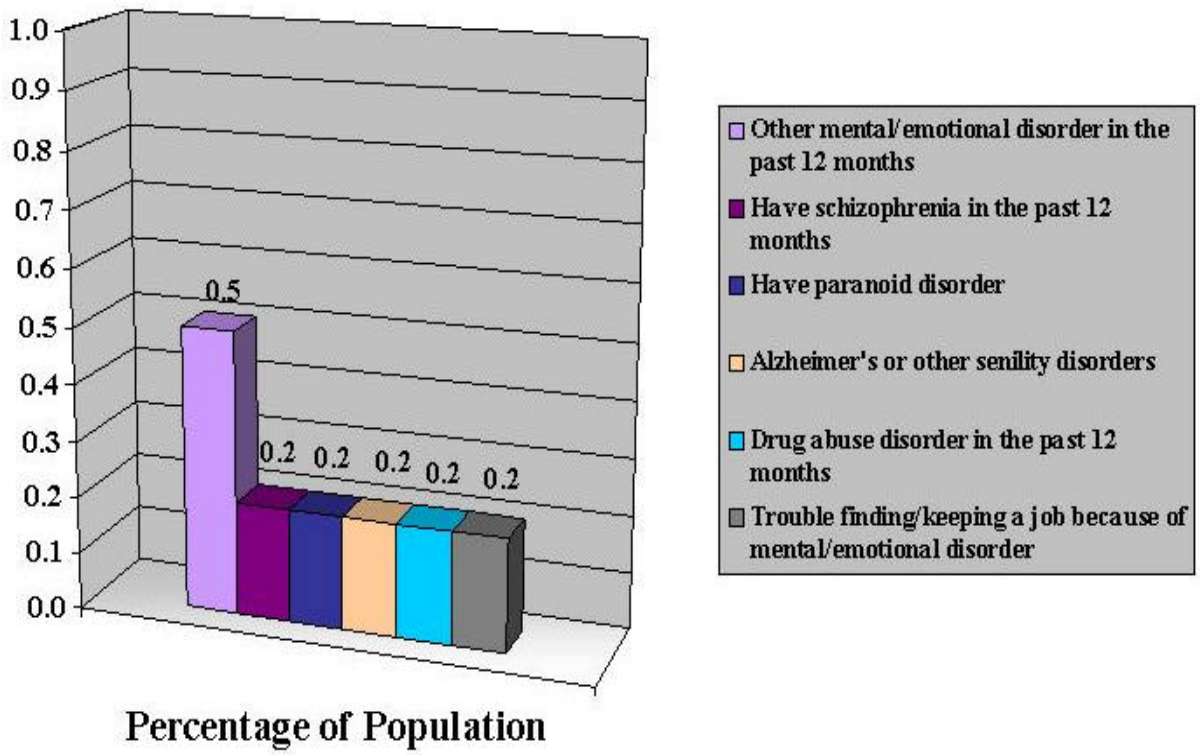
National Study of Health and Disability
Prevalence in Population 18 Years & Older



National Study of Health and Disability
Prevalence in Population 18 Years & Older



National Study of Health and Disability
Prevalence in Population 18 Years & Older



APPENDIX C*

Council of Regional Networks for Genetic Services (CORN):

Guidelines for Clinical Genetic Services for the Public's Health (GCGS)

***This document is a downloadable PDF file provided by the Council of Regional Networks for Genetic Services (CORN). The Bowen Research Center is not responsible for its content or typographical errors. It is provided for source and information purposes**

http://www.emory.edu/PEDIATRICS/corn/news/pubs.htm

APPENDIX D

Key Informant Questionnaire

Key Informant Questionnaire

1. What is your perception \ opinion of access to services for citizens with birth defects and genetic conditions in Indiana?

2. What is \ are the barriers to access to services for citizens with birth defects and genetic conditions in Indiana?

3. What is your perception \ opinion of the quality of services available to citizens with birth defects and genetic conditions in Indiana?

4. What educational tools do you think would optimize the patient's understanding of the genetic information provided to them via a care provider?

5. How do you perceive the adequacy of the training of the medical community to meet the needs of clients with birth defects and genetic conditions in Indiana?

6. Do you believe the clinical provider \ physician providing care following birth is trained to identify birth defects and genetics conditions?

7. Do you believe the clinical provider \ physician providing care has enough information about services to make the needed referrals?

8. Are there enough physicians, other clinical providers and Genetics Counselors to meet the service needs of clients with birth defects and genetic conditions?

9. What improvements \ expansions in the health care system, if any, are needed to better meet the service needs of citizens with birth defects and genetic conditions in Indiana?

10. What improvement in financial support, if any, are needed to meet the service needs of citizens with birth defects and genetic conditions in Indiana?

APPENDIX E

Protocol for
Key Informant Interviews

Protocol for Key Informant Interviews

Telephone Guidelines

- ?? Try using the Suvon procedure first – on every call. Suvon is a system designed to call areas that are commonly long distance, but the University is not charged long distance fees.
- ?? The procedure
- ?? Dial 16 – 1 (area code) (phone number)
- ?? If Suvon is not available
- ?? Dial 9 – 1 – (area code) (phone number)
- ?? You will be directed to enter your access code

Establish rapport

- ?? Give an explanation of the purpose of the interview.
- ?? Give the intended use of the information being gathered.
- ?? Assure the informant of confidentiality.
- ?? Give assurance that the interview has been approved by relevant officials.
- ?? Avoid jargon.

Use only open-ended questions phrased carefully to elicit detailed information.

- ?? Ask only one question at the time.
- ?? Avoid questions that contain embedded parenthetical phrases.
- ?? Be sure to wait after asking a question—the informant may require some time to think avoid rephrasing questions.

Use probing techniques.

- ?? Encourage informants to detail the basis for their conclusions and recommendations.
- ?? Elicit elaboration with the use of silence or with "tell me more" statements.

Maintain a neutral attitude. Neutrality is essential because some informants will try to be polite and will say what they think the interviewer wants to hear.

Be sympathetic to the listeners and avoid giving the impression of strong views on the subject under discussion.

Take notes and develop them in detail immediately after each interview to ensure accuracy.

Use a set of common subheadings for interview texts (eases data analysis).

Include

- ?? Interview summary sheet
- ?? Prepared into manageable themes, issues, and recommendations.
- ?? Each summary should provide
    - Key informants (KI) position
    - reason for inclusion in the list of informants
    - main points made
    - implication of these observations
    - any insights or ideas the interviewer had during the interview.

APPENDIX F

Telephone Call Scripts:

Script 1 & Script 2

Telephone Call Scripts

Script 1 – Initial Phone Call

?? Phone Call

- Hello (Dr. Smith), my name is _____and I am a research assistant from the IU Bowen Research Center. We (IU BRC) have been asked by the (ISDH) State to evaluate birth defects and genetic conditions services in Indiana. Your name was given to us by the State as a person who has knowledge about this issue and we like to include your thoughts in our assessment. The data (answer to questions) will be aggregated for reports, but your individual information will be kept confidential. If you are willing to participate, I would like to email or fax the question list so you have some time to gather your thoughts. I would also like to schedule ½ hour of your time to talk with you over the phone regarding your thoughts in the very near future.

- Although it is not necessary, it would be very helpful if you wrote down your major points and emailed or faxed them back for our discussion and \ or write-up.

- May I have your email address (fax number….) to send a copy of the list of questions?

- Thank you for your time, I will be calling on _____ .

?? **Schedule telephone interview.**

?? **Email or fax both pages of the survey.**

Script 2 – Interview Phone Call

?? Hello again (Dr. Smith), I am _____ from the IU Bowen Research Center working the ISDH on the Indiana genetics research study. As you may recall, your answers to these questions are part of a larger needs assessment designed to examine the current status of genetic services and data information systems in Indiana. Thank you again for taking time out of your schedule to assist us in this project by participating in this interview. Please remember your individual responses will be kept confidential. I will begin by asking a set of predetermined questions, which you should have received by now, and then documenting your answers. If you are not comfortable with any portion of this interview, please let me know and we will skip to the next question. I may ask other questions that were not included on the original questionnaire in order to capture an accurate and complete response to the issue. In the event that further information or clarification is necessary, may I contact you again for assistance?

?? **Conduct the interview**
Ask questions and document the result

?? **Conclusion Statement**
"We have now completed our interview. Do you have any questions, concerns, or additional comments you would like noted?"

?? **Closing**
"Thank you for your patience, for your time and for being a part of this study. Please keep in mind that should we need any additional information we will be in contact with you.

"Have a good day."